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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,809	05/04/2001	Mark W. Perlin	PERLIN-10	8918

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EXAMINER

SMITH, CAROLYN L

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 03/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/849,809

Applicant(s)

PERLIN, MARK W.

Examiner

Carolyn L Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,8,9,11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,8,9,11 and 12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendments and remarks, filed 12/17/04, are acknowledged. Amended claims 1 and 11 are acknowledged.

Applicant's arguments, filed 12/17/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-4, 8-9, and 11-12 are herein under examination.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 8-9, and 11-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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Applicant has not pointed to any section in the specification, claims, or drawings, as originally filed that provide written support for the phrase “that does not directly correspond to a length of a labeled nucleic acid product” as currently amended into instant claims 1 and 11. It is noted that negative limitations must be supported by the originally filed application. Because the introduction of the phrase “that does not directly correspond to a length of a labeled nucleic acid product” does not appear to have written support, this phrase is considered to be NEW MATTER. Claims 2-4, 8-9, and 12 are also rejected due to their dependency from claims 1 and 11. This rejection is necessitated by amendment.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 8-9, and 11-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is necessitated by amendment.

Claims 1 and 11 recite the phrase “that does not directly correspond to a length of a labeled nucleic acid product” which is vague and indefinite. It is unclear what parameters and to what degree these parameters must be met to be considered to not be in direct correspondence with the length. Clarification of this issue via clearer claim wording is requested. Claims 2-4, 8-9, and 12 are also rejected due to their dependency from claims 1 and 11. This rejection is necessitated by amendment.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 8, 9, and 11 are rejected under 35 U.S.C. 102(b) and (e)(2) as being anticipated by Ruano (P/N 5,427,911).

Ruano disclosed the combined or coupled methods of amplification and sequencing of DNA in both the title and abstract that is also the subject matter of the instant claims. The utilization of this methodology of the reference for criminal justice is described in column 3, lines 45-52, wherein law enforcement is cited which is deemed equivalent to the criminal justice usage as the instantly elected specie of invention. Identification for such law enforcement purposes inherently utilizes a database of genetic variations or polymorphic data as required also in instant claim 9. All of the summarized methods in column 1, line 59, through column 4, line 53, start with amplification that is also the first step in instant claim 1. These methods utilize primers as described specifically in the examples in columns 9-12, as well as chain terminating nucleotide analogs labeled to produce a collection of labeled nucleic acids products as also instantly claimed in claim 1, part (b). Size separation of the products is disclosed in the reference via electrophoretic methodology on sequencing gels as set forth, at various citations, for example, in column 10, lines 26-30. The detection of the total amount of label in said

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products occurs via autoradiography as shown in Figures 1A through 1D and Figure 3 as pictorial measurement as in instant claim 1, part (c). The darkness of each band in each lane of said Figures corresponds to the amount of terminating nucleotide which has been incorporated into labeled product as also required in instant claim 2. Each lane of said Figures also corresponds to a length of DNA sequence in sample DNA as may be read off for sequence determination as in standard sequencing procedures as also required in instant claim 3. The Figures depict a plurality of bases in the DNA sequence of the sample as also required in instant claim 4. Each lane in these Figures is a collection as instantly claimed and the sequence information is derived from combining four lanes, one for each nucleotide type, to determine DNA sequence information about the sample, thus anticipating step (d) of claim 1 also. These means are also those of instant claim 11. Ruano et al. disclose in Figure 3 an optimization of a ratio of the terminator to the elongator of all four bases for a 300 bp fragment (col. 5, lines 17-22) which represents a measurement that does not directly correspond to a length of a labeled nucleic acid product, as stated in amended instant claims 1 and 11.

Thus, the instant claims are anticipated by the reference disclosure. This rejection is necessitated by amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ruano (P/N 5,427,911) as applied to claims 1-4, 8, 9, and 11 above; taken in view of Lander et al. (P/N 6,692,909).

Ruano has been summarized above as describing the basic instant invention. Ruano, however, does not specifically disclose the thermocycler or the combining means of instant claim 12.

The abstract of Lander et al. summarizes the invention therein disclosed as directed to the subject matter area of the instant invention as is Ruano as to applications of genetic sequence analysis. A major part of Lander et al. is directed to disease detection, however, the reference also includes the use of polymorphisms for crime scene investigation and for identification purposes as cited in column 10, line 29, through column 11, line 37, as is the elected specie of the instantly claimed invention. Lander et al. in column 17, line 38, through column 18, line 60, describe examples including the usage of thermocyclers as well as computer analysis to compare sequences which necessarily requires some type of memory of polymorphisms as required in instant claim 12. The automation of thermocyclers and computer analysis is motivated and suggested to improve the efficiency of analysis of large numbers of sequences in such genetic analyses.

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Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the Ruano amplification and sequencing with the improvement of automation involving thermocyclers and computer analysis as in Lander et al. to improve such analysis efficiency to result in a reasonable expectation of success in practicing the instant invention. This rejection is necessitated by amendment.

Applicant states they have amended claims 1 and 11 to distinguish his invention from the prior art. This statement is found unpersuasive as the added limitation can be interpreted broadly and reasonable so that the art still applies. The added limitation appears to be vague and indefinite (see 35 USC 112, 2nd paragraph rejection), such that it has been interpreted as being any measurement other than the length, such as a ratio (as disclosed in the Ruano et al. reference).

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

March 8, 2005

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
3/15/05